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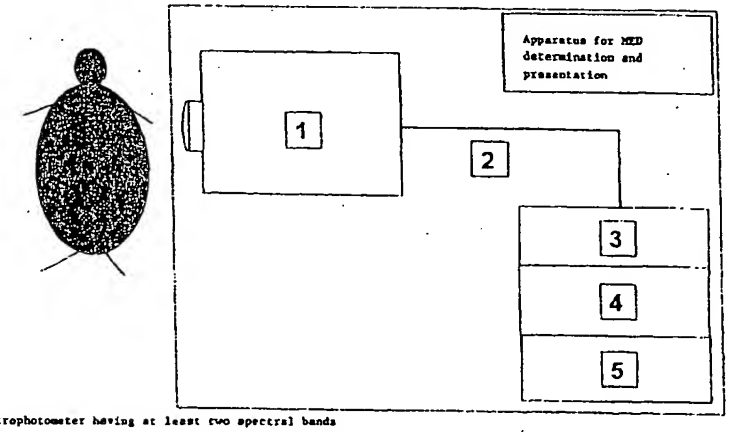
(54) Title: METHOD AND DEVICE FOR DETERMINING THE MINIMUM ERYTHEMATOUS AMOUNT RELATING TO HUMAN SKIN EXPOSURE TO ULTRAVIOLET RADIATION



1: Spectrophotometer having at least two spectral bands

2: Connecting means for transmission to data processing unit

3: Processing unit

4: Data storage and parameters

5: Display (e.g. MED-value, reflectance and other associated values such as exposure time associated with UV source)

(57) Abstract: A method of determining the minimal erythemal dose (MED) on exposing the skin of a subject to UV radiation, comprising the following steps: irradiating at least one region (P2) of any kind of the body skin of a subject (S) with at least two radiations, each in a different spectral band (a, b), at least one of which is correlatable only or mainly with the melanin amount present in the skin; carrying out the reflectance (or absorbance) measurement relating to said bands at said irradiation point; calculating the value of the minimal erythemal dose (MED) as a function of the measurements carried out. And a device for putting the method into practice.

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METHOD AND DEVICE FOR DETERMINING THE MINIMUM ERYTHEMATOUS AMOUNT RELATING TO HUMAN SKIN EXPOSURE TO ULTRAVIOLET RADIATION

Description

Technical Field

The invention falls within the field of the methods and apparatus used for measurement and control of the amount of UV radiation in relation to the photodermatologic effects of the human skin. In more detail, the invention relates to a method and a device to be used in the field concerning treatments by UV radiation for therapeutical and aesthetic purposes, in order to determine the minimum erythematous amount, in the following referred to as MED (Minimal Erythemal Dose).

Prior Art

At the present state of the art, for determining the MED for a given skin region of a person, the method which is mostly used is that of photo tests: a controlled irradiation of increasing doses of UV rays is carried out so as to evaluate the different skin reactions. Also known in the scientific literature are methods correlating the MED with data acquired through a specific questionnaire, typically by defining different classes of skin types (phototypes).

Other methods use the reflectance measurement, defined as the electromagnetic radiation fraction incident on the skin surface reflected by diffusion from the skin itself (it is therefore the fraction that is not reflected in mirror image relationship from the surface), bound to the amount of melanin present in the patient's skin.

However, the known methods and apparatus do not solve the problem of a fully reliable characterization of the MED value in a patient, both due to the great variability of this value for the same phototype and in particular due to the fact that until now it was not possible to individually consider the contribution of the natural constitutive photo protection of a skin that has not been previously irradiated and the contribution relating to an optional photo protection, i.e. induced by previous exposures such as for example afflux to the surface and/or production of melanin and increase in the skin thickness.

Object

A first object of the method and the device of the invention is therefore to enable a reliable and careful determination of the MED of any skin region in any subject or patient, in the real skin conditions of this subject at a given instant, capable of solving the drawbacks bound to use of traditional methods and apparatus.

Summary of the Invention

To this aim, in accordance with the invention, a method of determining the MED has been devised which comprises a set of at least two reflectance measurements, each relating to a different spectral band within the range of the visible light and the near infrared light (VIS/NIR) of the electromagnetic spectrum, at least one of which is correlated with the amount of melanin present in the skin. This set of measurements must be carried out at least in the skin portion of which the MED is wished to be determined, generally depending both on the optional pigmentation and skin thickening, resulting from possible

preceding exposures.

The measurement is preferably also carried out at a second skin region that can be taken as reference portion because it can be considered as never exposed to UV radiation, i.e. in which the skin pigmentation and thickness can be assumed as exclusively dependent on the constitutive photo protective features of the subject and not affected by previous exposures to UV radiation.

The MED is therefore calculated based on the at least two reflectance values obtained (four values in the preferred case).

The invention further relates to a device for putting the method into effect, comprising a spectrophotometer for at least the two reflectance measurements or other magnitudes directly correlatable therewith (e.g. absorbance), and a calculating unit and possibly a data storing unit, interfaced and/or integrated with said spectrophotometer for calculation of the corresponding MED.

The obtained advantages essentially consist in reliability, efficiency and high personalisation in determining the MED. Personalization is due in particular to the fact that the set of measurements carried out on the reference portion of the patient's skin (the skin portion that can be assumed as previously not exposed to UV radiation) is associated with the constitutive skin features, whereas the set of measurements carried out in the other portion takes into account the current conditions of the skin itself in the real exposure conditions (e.g. optional photo protection).

Brief Description of the Drawings

The foregoing and further advantages will be better understood by a person of ordinary skill in the art from the following description and the accompanying drawings, given by way of non-limiting example, in which:

- Fig. 1 shows the graph of a possible course of the MED in accordance with the method of the invention for different phototypes;
- Fig. 2 shows a table of the phototypes traditionally used in accordance with DIN-5050 standards;
- Fig. 3 shows the absorption spectra of some typical substances present in the human skin and the band selection criterion for the reflectance (absorbance) measurements;
- Fig. 4 diagrammatically shows accomplishment of a method of an aesthetic treatment in accordance with the invention on a patient in a first UV-exposure session;
- Fig. 5 diagrammatically shows accomplishment of the method in Fig. 4 in a UV-exposure session following the first one;
- Fig. 6 diagrammatically shows a device in accordance with the invention.

Description of the method

In a preferred embodiment, the method of determining the minimal erythemal dose, MED, in accordance with the invention contemplates carrying out, at different points P1, P1', P2 of the body of a subject S, at least two reflectance (or absorbance) measurements, each relating to a different spectral band within the spectral range of the visible and near infrared (between 400 and 1400 nm) electromagnetic spectrum (VIS/NIR), of which at least one is only or mainly correlatable with the amount of melanin present in the skin.

This means that for this band, absorption due to melanin

can be considered as prevalent with respect to other causes such as haemoglobin or beta-carotene for example (see Fig. 3 in the neighbourhood of 660 nm).

To calculate the MED, at least one first point P1 and/or P1' is considered in a skin portion (gluteus or under-axilla region, for example) that is deemed to have never been previously exposed to UV radiation so as to give an indication of the patient's constitutive photo protection (see Fig. 4), as well a second point P2 of a skin portion, a point that, for example, can be judged the maximum exposure point of the patient for the concerned exposure conditions (taking into account the skin/UV relative source position, for example, and the spatial emission features of the UV source, be it an artificial or a natural source), in which the photo protection features also depend on the reactions induced by possible previous exposures to UV rays.

For measurement, preferably a spectrophotometer is used which is capable of measuring the reflectance (R_λ) relating to different spectral bands each characterized by a different wavelength λ, or equivalently the absorbance ($A_\lambda = 100\ Log_{10}\ (1/R_\lambda)$) or logarithm of the inverse of the reflectance ($LIR_\lambda = Log_{10}\ (1/R_\lambda)$), such as in the case of the spectrophotometer produced by Diastron Limited (GB).

On defining the following parameters, reference being made for expository convenience to the case of a set of measurements limited to two spectral bands alone, "α" and "β", at all events belonging to the spectral range VIS/NIR identified as:

$R_{\alpha,1}$ reflectance measurement in the spectral band α, for point P1 and/or P1'

$R_{\beta,1}$ reflectance measurement in the spectral band β, for

point P1 and/or P1'

$R_{\alpha,2}$ reflectance measurement in the spectral band α, for point P2

$R_{\beta,1}$ reflectance measurement in the spectral band β, for point P2

the following algorithm is followed:

1) Calculation of absorbances from reflectances R (e.g. $A = Log_{10} (1/R)$

2) Linear combination (LinC) of absorbances A relating to the set of spectral measurements for each skin point Pi taken into account that, in the case of two spectral bands alone α and β, is:

$$LinC = k_{\alpha,1} \cdot A_{\alpha,1} + k_{\beta,1} \cdot A_{\beta,1} + k_{\alpha,2} \cdot A_{\alpha,2} + k_{\beta,2} \cdot A_{\beta,2} + k$$

wherein $A_{\lambda,n}$ is the absorbance measured at point n for the wavelength band λ, and the values of the real constants $k_{\lambda,1}$ depend on the particular spectral bands therein utilized. If the reference point or points of type 1 are not used, the coefficients of type $k_{\lambda,1}$ and $A_{\lambda,1}$ are absent.

Should several points of type 1 (e.g. P1 and P2) be present for each spectral band λ, the average or minimum value of the absorbances obtained for the different points is considered.

3) Polynomial relation between the MED value relating to point P2 and the linear combination obtained (LinC) : [Eq. 1)

$$MED_{P2} = poly\ (LinC)$$

wherein the degree and value of the polynomial coefficients can be different depending on the considered spectral bands.

It is understood that the relation between MED and LinC can be expressed following any statistical correlation method, for example a neural network calibrated on the basis of a record of cases of LinC/MED values.

In an example for putting the method into practice, reflectance measurements for the spectral bands relating to the green light (568 nm) and the red light (655 nm) have been utilised. In the last-mentioned band melanin absorption is in fact high, whereas absorption due to other substances, such as haemoglobin, can be considered as negligible. In the current example therefore the absorbance in the red light A_{red} and that relating to the green light A_{green} are taken into account for point P1 and point P2. Shown in Fig. 3 is the distribution of a number of MED measurements (expressed in effective erythemal J/m^2) for different patients, carried out by photo test (circular points) and of the corresponding MED values provided in accordance with the exposed method (square points).

In this application, the formula Eq. [1] has shown a correlation coefficient greater than 0.85 and a mean error of about 10% with respect to the MED value obtained from the photo test.

Preferably, also introduced into the relation Eq. [1] is a parameter K_{anam} which is drawn from the patient's photodermatologic anamnesis and which enables the correlation of the found relation to be further improved.

In accordance with the invention, the described method finds a particularly advantageous use in the field of cosmetic and possibly therapeutical treatments applied to a subject, which are based on UV radiation. In this case, the method comprises a further step of irradiating the patient with a controlled dose of UV rays lower than or equal to the MED calculated with the above described method, supposing that the patient does not suffer from pathologies, has not taken photosensitizing substances and did not expose himself/herself to UV radiation out of

the treatment. Preferably also provided is a step of recording the data of a patient who is destined to a subsequent exposure session.

In particular, for a patient who is submitted to a UV radiation for the first time, the method preferably contemplates the following steps (Fig. 4):

a) initializing a personalized file for the patient, DB;

b) carrying out a photodermatologic anamnesis of the patient and assigning a corresponding value of the parameter K_{anam} and/or a first estimate of the MED (MED_{anam}), and recording the data to DB;

c) executing the set of the reflectance (absorbance) measurements at a point P2 of a patient's skin portion that can be considered as a portion of maximum exposure based on the patient's irradiation conditions depending on the features of irradiance and geometry of the UV source utilized and the patient's arrangement relative thereto;

d) possibly, carrying out the set of reflectance (absorbance) measurements at least at one point P1, P1' of a skin portion that substantially has never been exposed to a UV radiation;

e) calculating the MED by the described method, based on the data drawn from the previous steps b), c) and possibly d).

When determination of the MED has been carried out, the patient can be irradiated, except for regions of type 1 (P1 and P1') with a smaller dose than the MED without causing erythema.

f) updating file DB with at least the data relating to step d) if carried out, and the data of the dose and date and hour of the possible UV administration.

In the sessions following the first one the method contemplates the steps of (Fig. 5):

c') repeating the procedure described in the preceding step c);

e') calculating the MED based on the data in DB and from step c');

Based on the time gap elapsed from the last administration the patient may possibly be enabled to be irradiated with a lower UV dose than the determined new MED value.

f) updating file DB with at least the date and hour of the possible new administration of UV dose.

Preferably, steps e), e') contemplate calculation of the MED based on the method described in the preceding paragraph.

Description of the Apparatus for Determination of the MED

The invention also relates to a device for carrying out the set of two or more reflectance (absorbance) measurements in accordance with the described method and outputting the value of the calculate MED.

With reference to Fig. 6, the device comprises a spectrophotometric unit 1 capable of being brought into side by side relationship with one or more points P1, P1', P2 of the patient's skin for the reflectance measurements and a connection 2 for transmission of the measured data to a processing unit 3 and possible storage 4 thereinto. Units 1, 2, 3 and possibly 4 can be also integrated into a single device. Preferably units 3 and 4 are a single microprocessing unit calculating the MED based on the described algorithm.

Preferably the device comprises a display 5 for showing data concerning the patient, such as MED, skin reflectances on two or more spectral bands, and indirect

data such as melanin index, erythemic exposure time t_{MED} for a source of known effective erythemal UV irradiance IrrUV, ...).

In addition to the measurement data relating to the patient, the data storage may also contemplate the effective erythemal UV irradiance data IrrUV relating to one or more UV sources, on the basis of which the minimal erythemal exposure time t_{MED} is calculated:

$$t_{MED} = MED/IrrUV \quad \text{(Eq. 2)}$$

in which the appropriate measurement units are utilized (e.g. [MED] = J/m^2, [IrrUV] = W/n^2, [^tMED] = s).

The present invention has been described with reference to preferred embodiments but it is understood that equivalent modifications can be made by a person skilled in the art without departing from the protective scope of the appended claims.

C L A I M S

1. A method of determining the minimal erythemal dose (MED) in exposing the skin of a subject to UV radiation, comprising the following steps:
- irradiating at least one region (P2) of the body skin of a subject or patient (S) generally characterized by both constitutive and optional photo protection with at least two radiations, each in a different spectral band (a, b) within the spectral range of the electromagnetic visible and near infrared spectrum approximately between 400 and 1400 nm (VIS/NIR), at least one of said radiations being only or mainly correlatable with the melanin amount present in the skin;
- carrying out the measurement of the reflectance (absorbance) relating to said bands at said irradiation point;
- calculating the value of the minimal erythemal dose (MED) at (P2) as a function of the carried out reflectance measurements (R).

2. A method as claimed in claim 1, wherein in addition to the reflectance measurements relating to point (P2), also considered are the reflectance values according to steps a and b on one or more skin regions of the patient (P1, P1') that normally have never been exposed to UV radiation, in which pigmentation can be supposed to be exclusively of the constitutive type.

3. A method as claimed in claim 1 or 2, wherein said (MED) is calculated in the form of a polynomial relation
MED = poly(LinC) (Eq. [1]),
$LinC = k_{a,1} \cdot A_{a,1} + k_{b,1} \cdot A_{b,1} + k_{a,2} \cdot A_{a,2} + k_{b,2} \cdot A_{b,2} + k$
wherein (ai,j) is the absorbance measured at points Pj (P1,2) for the frequency band i (a, b), and (k, k_{ij}) are real constants depending on the at least spectral bands

(a, b) that have been utilized.

4. A method as claimed in claim 3, wherein in the case of several points of type (P1, P1') for each spectral band λ, the average or the minimum one of the values of the absorbances obtained for the different points is considered.

5. A method as claimed in claim 1, wherein said reflectance measurements are carried out in the spectral bands relating to the green light (e.g. wavelength 568 nm) and the red light (e.g. wavelength 655 nm).

6. A method as claimed in one or more of the preceding claims wherein at least one of said reflectance measurements is correlated with the haemoglobin amount present in the irradiated region of the patient's skin.

7. A method of treating a patient through UV radiation, comprising the following steps:
- carrying out the reflectance (absorbance) measurements at a point (P2) of a patient's skin portion that can be considered as a portion of maximum exposure based on the patient's irradiation conditions depending on the features of irradiance and geometry of the UV source utilized and the patient's arrangement relative thereto;
- calculating the MED based on the data drawn from the preceding steps and exposing the patient to UV irradiation, except for the regions (P1 and P1'), in a dose lower than or equal to the MED.

8. A method as claimed in claim 7, wherein in said step of measuring the reflectance, also reflectance (absorbance) measurements are carried out at least at one point (P1, P1') of the patient's skin that substantially has never been exposed to a UV radiation.

9. A method as claimed in claim 7 or 8, wherein a preliminary step is included which involves initialization of a personalized file (DB) for the patient.

10. A method as claimed in claim 8 or 9, wherein a step of updating file DB with at least the measurement data on said points (P1, P1') is included.

11. A method as claimed in claim 9 or 10, wherein a step is included which consists in carrying out a photodermatologic anamnesis of the patient and assigning a corresponding value of the parameter K_{anam} and/or a first estimate of the MED (MED_{anam}), and recording the data to file DB.

12. A method as claimed in claim 9, wherein several treatment sessions are provided and wherein in sessions subsequent to the first one provision is made for the steps of calculating the MED based on data in (DB) and the step of calculating the MED and updating file DB with at least the date and hour of the possible new UV dose administration.

13. A method as claimed in one or more of claims 7 to 12, wherein the steps of calculating the MED are carried out based on the method as claimed in claims 1-6.

14. A method as claimed in claim 12, comprising a step of controlling the time gap elapsed from the last administration based on which the subject can possibly be enabled to be irradiated with a lower UV dose than the determined new MED value.

15. A device for calculating the MED for a subject submitted to UV radiation, characterized in that it

comprises:
- a spectrophotometric unit (1) of at least two spectral bands (a, b), capable of being brought into side by side relationship with one or more points (P1, P1', P2) of the patient's skin for the reflectance measurements;
- a connection (2) for measurement transmission to a data processing unit (3) for calculating the (MED) and other magnitudes (e.g. minimal erythemal exposure time) based on measurement data received from said unit (1);
- a memory (4) for inputting to a file (DB) and updating the personal measurement data of one or more patients from a spectrophotometer (1) and the features of one or more UV sources (e.g. UV irradiance) to be used for administration of the dose, wherein said processing unit (3) comprises means for calculating the MED according to one or more of claims 1-6.

16. A device as claimed in claim 15, wherein the units (1, 2, 3 and 4) are integrated into a single body.

17. A device as claimed in claim 15, wherein the units (3) and (4) are integrated into a single microprocessing unit with memory, provided with means for calculating the MED and possibly other magnitudes derived from the measurements and/or parameters stored therein such as melanin index, minimal erythemal exposure time for a given source of a stored or assigned effective erythemal UV irradiance IrrUV: tMED = MED/Irr UV (eq. 2).

18. A device as claimed in claim 15, comprising a display (5) showing the data relating to the patient, as well as the calculated magnitudes.

19. An apparatus for administration of UV doses to a subject comprising:
- a device for measurement of the MED according to at

least one of claims 15-18;

- at least one UV source for controlled administration of a dose not exceeding the MED calculated for the subject.

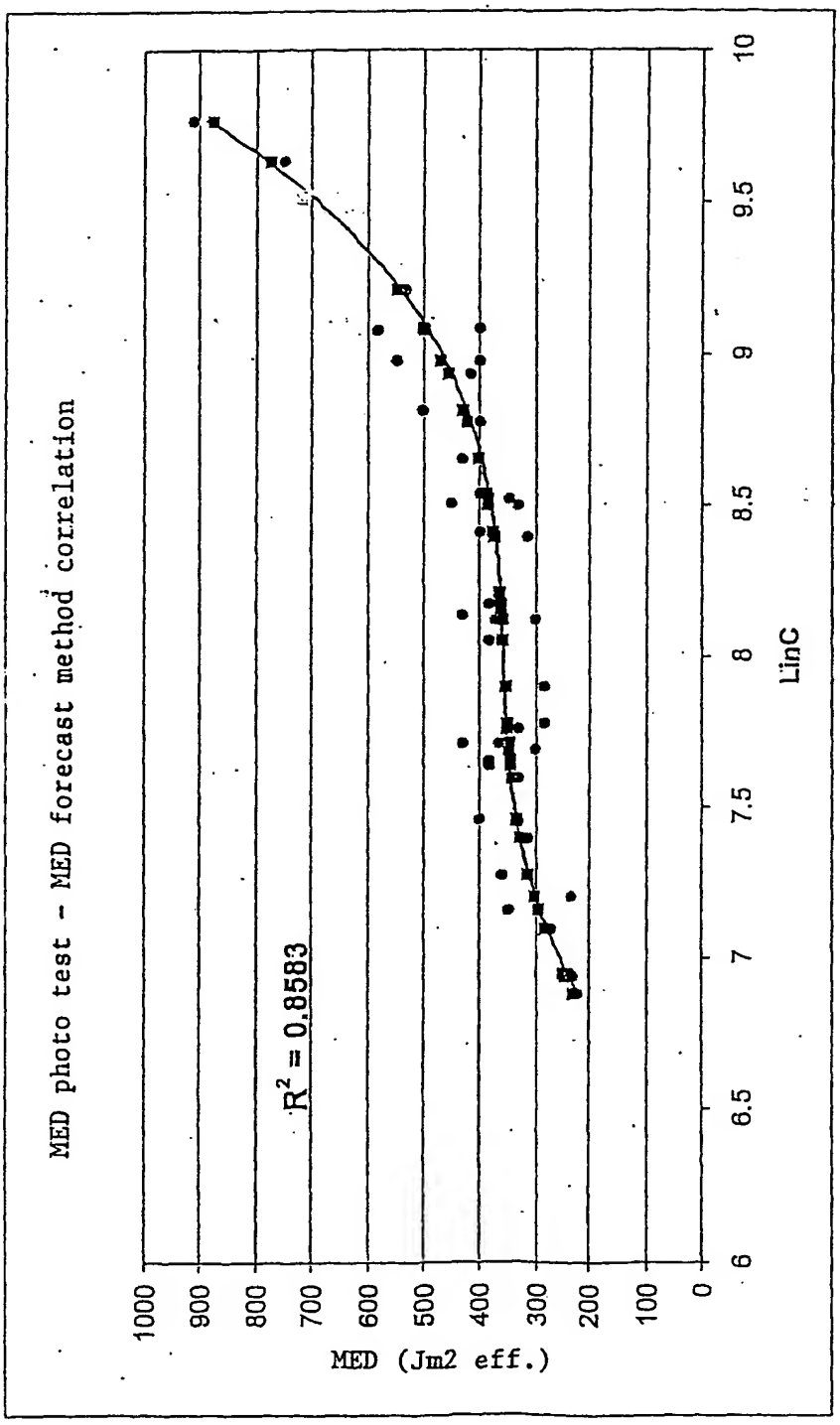

MED photo test - MED forecast method correlation
R^2 = 0.8583
MED (Jm2 eff.)
1000
900
800
700
600
500
400
300
200
100
0
LinC
10
9.5
9
8.5
8
7.5
7
6.5
6

FIGURE 1

Phototype	Tan	Burn	Hair	Eyes	MED (J/m2)
I	never	always	red	blue	200
II	sometimes	sometimes	fair	blue/green	250
III	always	seldom	brown	grey/brown	350
IV	always	never	black	brown	450

FIGURE 2

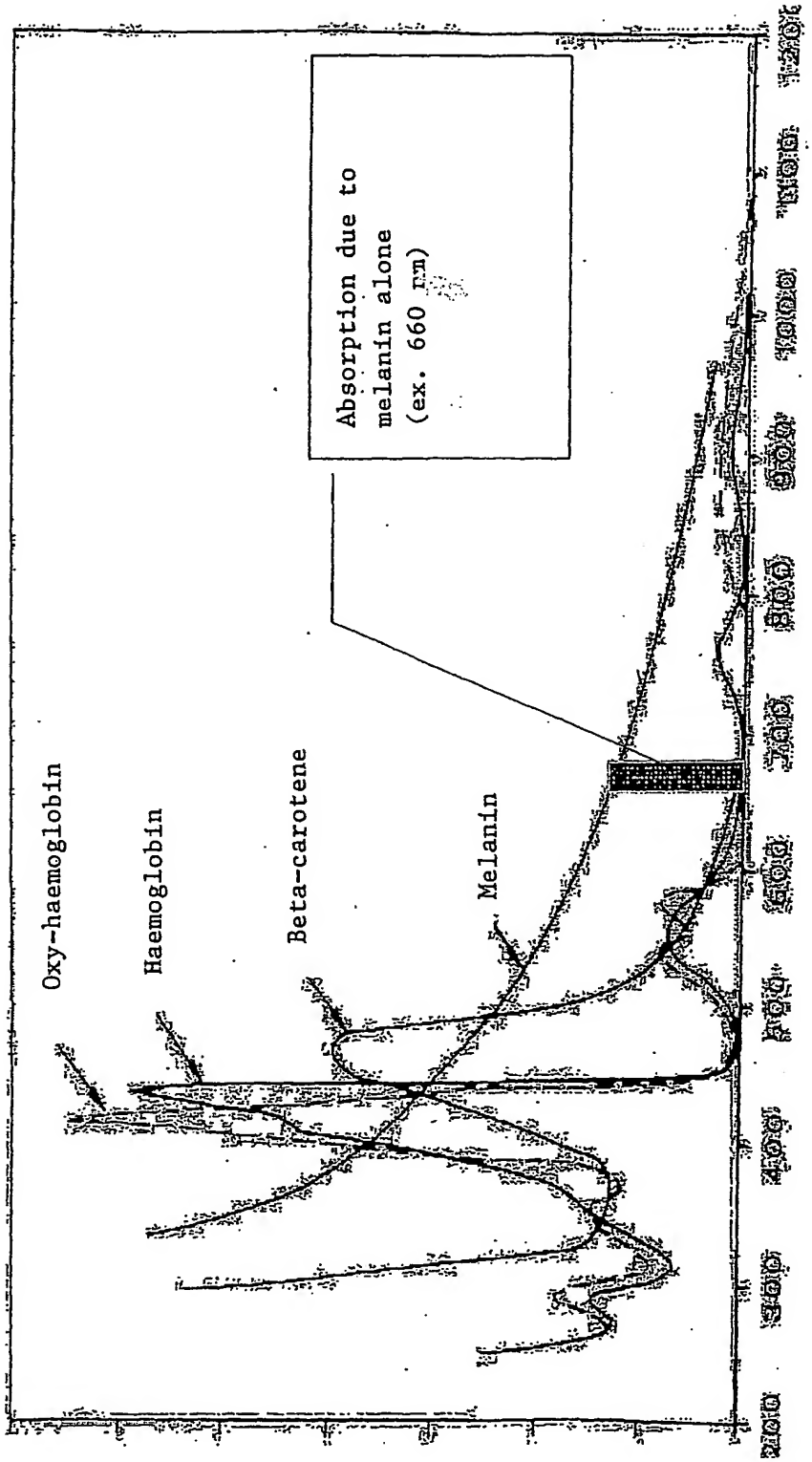

Absorption due to melanin alone (ex. 660 nm)
Oxy-haemoglobin
Haemoglobin
Beta-carotene
Melanin
Relative absorption
Wavelenght

FIGURE 3

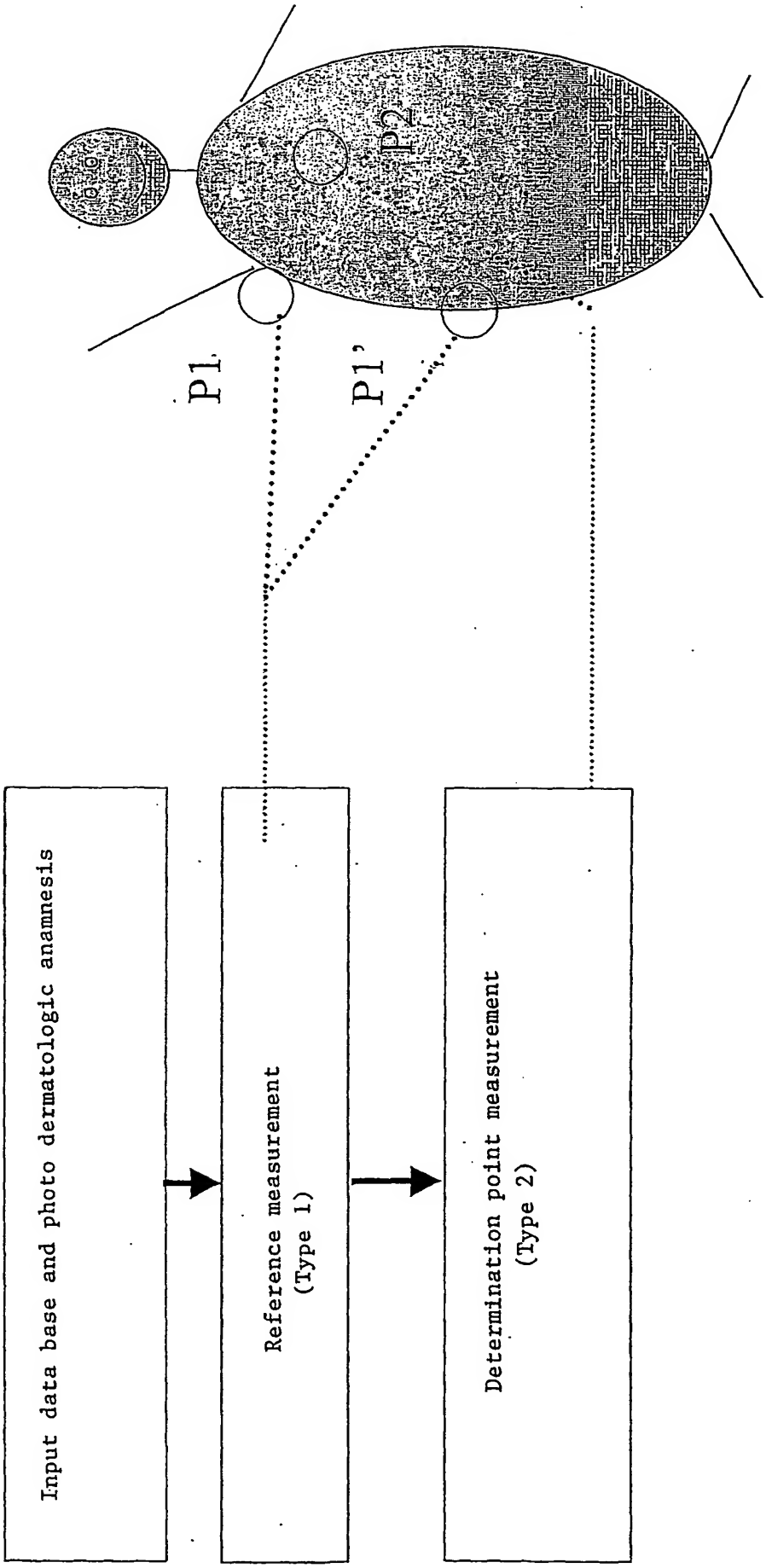
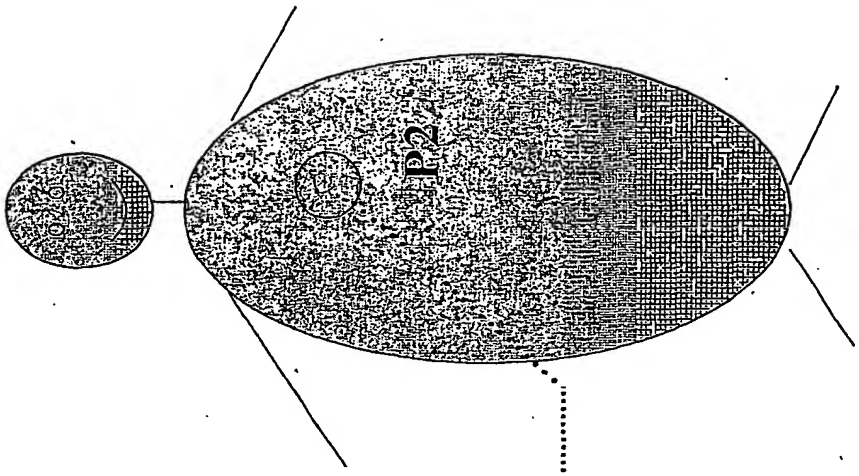
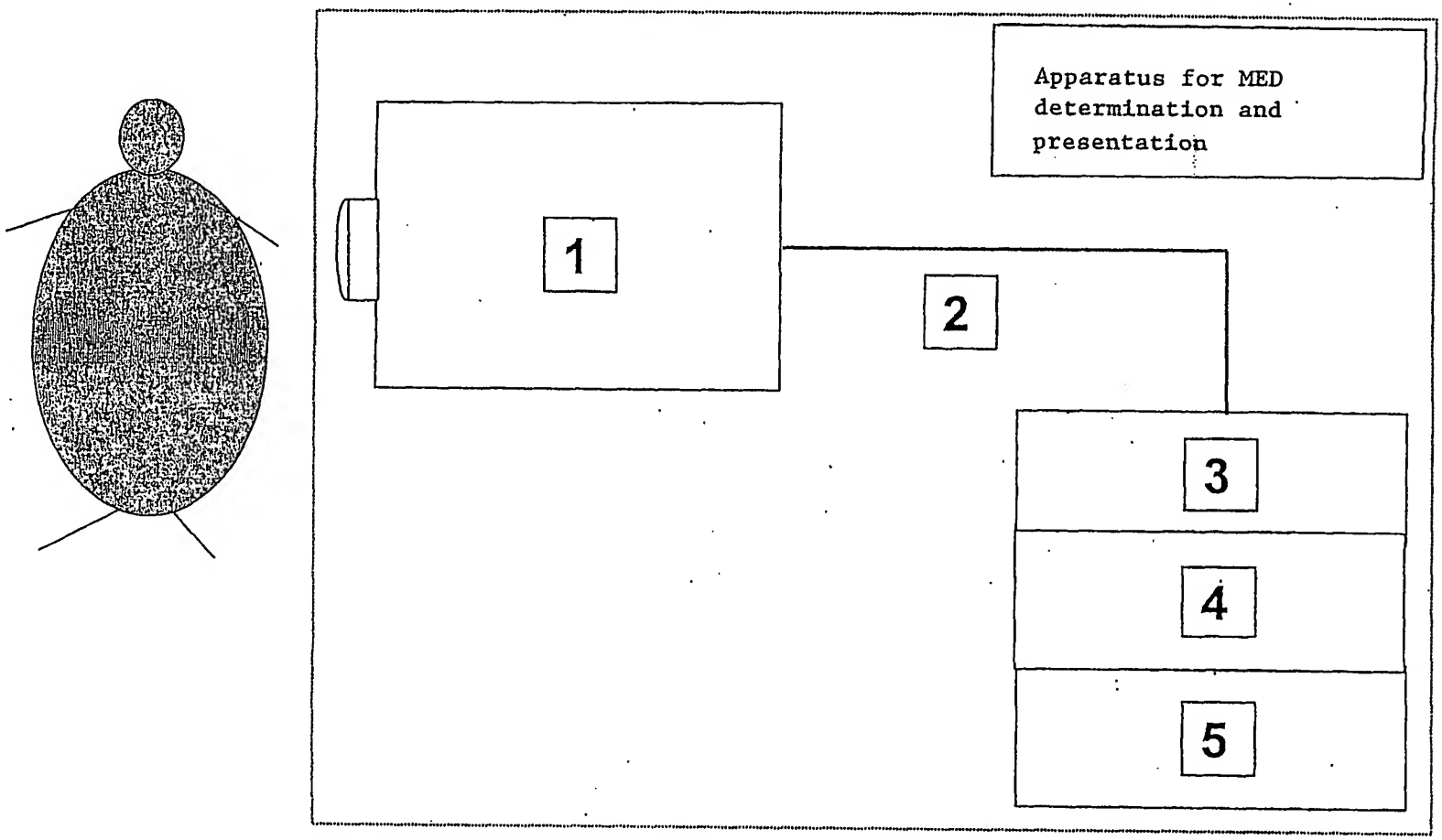

P2
P1
P1'
Input data base and photo dermatologic anamnesis
Reference measurement
(Type 1)
Determination point measurement
(Type 2)

FIGURE 4



Determination point measurement
MED
(Type 2)

FIGURE 5



1 : Spectrophotometer having at least two spectral bands

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5: Display (e.g. MED value, reflectance and other associated values such as exposure time associated with UV source)

FIGURE 6

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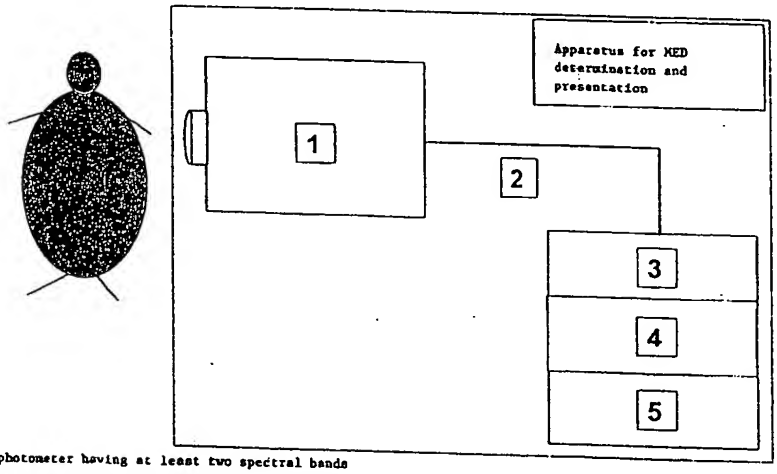

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4: Data storage and parameters

5: Display (e.g. MED value, reflectance and other associated values such as exposure time associated with UV source)

(57) Abstract: A method of determining the minimal erythemal dose (MED) on exposing the skin of a subject to UV radiation, comprising the following steps: irradiating at least one region (P2) of any kind of the body skin of a subject (S) with at least two radiations, each in a different spectral band (a, b), at least one of which is correlatable only or mainly with the melanin amount present in the skin; carrying out the reflectance (or absorbance) measurement relating to said bands at said irradiation point; calculating the value of the minimal erythemal dose (MED) as a function of the measurements carried out. And a device for putting the method into practice.

WO 03/030707 A3

INTERNATIONAL SEARCH REPORT

Interi ilication No
PCT/FI 02/00629

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/103 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93 16635 A (CHROMO LIGHT APS) 2 September 1993 (1993-09-02) page 10, line 9 -page 15, line 29; claims 1-10; figures 4,5	1,2,5,6, 15-19
X	US 4 882 598 A (WULF HANS C) 21 November 1989 (1989-11-21) column 3, line 1 -column 5, line 40	1,2
X	US 5 636 637 A (DE RIGAL JEAN ET AL) 10 June 1997 (1997-06-10) column 7, line 33 -column 8, line 27	1
A	US 4 423 736 A (DEWITT DAVID P ET AL) 3 January 1984 (1984-01-03) the whole document	1,15,19

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 February 2003	19/03/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Petter, E

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 297 22 723 U (MENZEL EBERHARD PROF DR ;SIPPEL RUEDIGER (DE)) 22 April 1999 (1999-04-22) the whole document	1,15
A	KRUTMANN J; HÖNIGSMANN H.: "Handbuch der dermatologischen Phototherapie und Photodiagnostik" 1997 , SPRINGER VERLAG , BERLIN XP002231586 page 314 -page 315 page 362 -page 367	1,15,19
A	SCHMIDT W-D ET AL: "NON-CONTACTING DIFFUSE VIS-NIR SPECTROSCOPY OF HUMAN SKIN FOR EVALUATION OF SKIN TYPE AND TIME-DEPENDENT MICROCIRCULATION" PROCEEDINGS OF THE SPIE, SPIE, BELLINGHAM, VA, US, vol. 4160, 6 July 2000 (2000-07-06), pages 91-102, XP008008978 the whole document	1,15,19
A	FEATHER J W ET AL: "A portable reflectometer for the rapid quantification of cutaneous haemoglobin and melanin" PHYSICS IN MEDICINE AND BIOLOGY, TAYLOR AND FRANCIS LTD. LONDON, GB, vol. 33, no. 6, June 1988 (1988-06), pages 711-722, XP002186027 ISSN: 0031-9155 the whole document	1,15,19
P,X	EP 1 170 035 A (KONINKL PHILIPS ELECTRONICS NV) 9 January 2002 (2002-01-09) the whole document	1,15-19
P,X	US 6 452 188 B1 (CHUBB CHARLES R) 17 September 2002 (2002-09-17) column 8, line 66 -column 10, line 34	1

INTERNATIONAL SEARCH REPORT

Int al application No.
PCT/IT 02/00629

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 7-14
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Inter ...lication No
PCT/IT 02/00629

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9316635	A	02-09-1993	DE	69319585 D1	13-08-1998
			DE	69319585 T2	15-04-1999
			WO	9316635 A1	02-09-1993
			EP	0629124 A1	21-12-1994
US 4882598	A	21-11-1989	AT	109668 T	15-08-1994
			DE	3650024 D1	15-09-1994
			DE	238574 T1	30-06-1988
			DK	269887 A	25-05-1987
			WO	8701948 A1	09-04-1987
			EP	0238574 A1	30-09-1987
			NO	872211 A	27-07-1987
US 5636637	A	10-06-1997	FR	2719989 A1	24-11-1995
			AU	684003 B2	27-11-1997
			AU	2005295 A	30-11-1995
			CA	2149600 A1	21-11-1995
			EP	1183995 A2	06-03-2002
			EP	1264578 A2	11-12-2002
			EP	0682912 A1	22-11-1995
			JP	3269750 B2	02-04-2002
			JP	7313468 A	05-12-1995
US 4423736	A	03-01-1984	NONE		
DE 29722723	U	22-04-1999	DE	29722723 U1	22-04-1999
EP 1170035	A	09-01-2002	EP	1170035 A2	09-01-2002
			US	2002022868 A1	21-02-2002
US 6452188	B1	17-09-2002	NONE		

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